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November 10, 2003

GROUP: 1635

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ATTORNEY DOCKET NO.: ISPH-0613

SERIAL NO.: 10/054,313

FILED: October 22, 2001

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(including this sheet)

MESSAGE: Attached is an Amendment Transmittal Letter (in duplicate) and
Reply to Restriction Requirement dated October 9, 2003.

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* * * * *

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AMENDMENT TRANSMITTAL LETTER (Large Entity)

Applicant(s): Crooke et al.

Docket No.
ISPH-0613Serial No.
10/054,313Filing Date
October 22, 2001Examiner
James SchultzGroup Art Unit
1635

Invention: HUMAN RNASE H AND COMPOSITIONS AND USES THEREOF

TO THE COMMISSIONER FOR PATENTS:

Transmitted herewith is an amendment in the above-identified application.

The fee has been calculated and is transmitted as shown below.

CLAIMS AS AMENDED

	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST # PREV. PAID FOR	NUMBER EXTRA CLAIMS PRESENT	RATE	ADDITIONAL FEE
TOTAL CLAIMS	45 -	45 =	0	x \$18.00	\$0.00
INDEP. CLAIMS	19 -	19 =	0	x \$86.00	\$0.00
Multiple Dependent Claims (check if applicable)					\$0.00
		TOTAL ADDITIONAL FEE FOR THIS AMENDMENT			\$0.00

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- Please charge Deposit Account No. _____ in the amount of _____.
- A check in the amount of _____ to cover the filing fee is enclosed.
- The Director is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-1619
- Any additional filing fees required under 37 C.F.R. 1.16.
- Any patent application processing fees under 37 CFR 1.17.

Jane Massey Licata

Signature

Dated: November 10, 2003

Jane Massey Licata
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cc:

CERTIFICATE OF TRANSMISSION BY FACSIMILE (37 CFR 1.8)

Applicant(s): Crooke et al.

Docket No.

ISPH-0613

Serial No.
10/054,313Filing Date
October 22, 2001Examiner
James SchultzGroup Art Unit
1635

Invention: HUMAN RNASE H AND COMPOSITIONS AND USES THEREOF

I hereby certify that this

Reply to Restriction Requirement

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NOV 10 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

OFFICIAL

Attorney Docket No.: ISPH-0613

Inventors: Crooke et al.

Serial No.: 10/054,313

Filing Date: October 22, 2001

Examiner: James Schultz

Group Art Unit: 1635

Title: Human RNase H and Compositions and Uses
Thereof

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On November 10, 2003

Jane Massay Licata
Jane Massay Licata Registration No. 32,257

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

REPLY TO RESTRICTION REQUIREMENT

This reply is to the Restriction Requirement mailed October 9,
2003, setting a one (1) month statutory period for response.
Please enter the following remarks into the record. No new matter
has been added by this response.

Remarks begin on page 2 of this paper.

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REMARKS

Claims 1-45 are pending in the instant application. The pending claims have been subjected to a Restriction Requirement under 35 USC §121 and 37 C.F.R. 1.141, as containing multiple independent sequences, comprising multiple inventions.

The Examiner suggests that there are five distinct inventions in the present application and requires restriction under 35 U.S.C. 121. The Examiner further suggests that present invention comprises five distinct groups:

Group I) Claims 1-13 and 22 drawn to an RNase H polypeptide that may be an RNase HI or type 2 RNase H polypeptide and compositions comprising pharmaceutical carriers or antisense and said RNase H, classified for example in class 435, subclass 183.

Group II) Claims 14-19, 24-26, 44 and 45 drawn to an isolated polynucleotide encoding RNase H which may be RNase HI or type 2 RNase H, and compositions comprising pharmaceutical carriers or antisense with said RNase H polynucleotide and vectors and cells thereof, and methods of use, classified in class 536, subclass 23.1.

Group III) Claim 20, drawn to an antibody targeted to a human type 2 RNase H, classified in class 530, subclass 387.1.

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Group IV) Claims 21,23, and 27-36, drawn to nucleic acid probes and antisense directed to human RNase H1 or human type 2 RNase H, and to methods of screening therefore, classified, for example, in class 536, subclass 24.5.

Group V) Claims 37-43, drawn to a method of identifying agents which increase or decrease activity of an RNase H polypeptide, classified for example in class 435, subclass 6.

The Examiner further suggests that groups I-V are unrelated to each other as they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.4, MPEP 808.01). The Examiner suggests that the different groups each comprise chemical structures which are independent of one another and not disclosed as capable of use together, and have different modes of operation. The Examiner further suggests that the polypeptide of Group I is not disclosed as being used in any method with either the polynucleotide of Group II or the antibody of Group III and that the polynucleotide of Group II is not disclosed as being used with the antibody of Group III. It is further suggested that the polypeptide of Group I is an enzyme that cleaves RNA/DNA hybrids, and functions differently than the polynucleotide of Group II and the antibody of Group III, which are not disclosed

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as having catalytic activity. The Examiner suggests that the antibody of Group III binds specifically to molecules based on complex tertiary structure, and that this feature is not shared by the polynucleotide of Group II.

The Examiner further suggests that the antisense of Group IV is unrelated to the polynucleotide of Group II and the antibody of Group III because the antisense molecules of Group IV are not disclosed as being used in any method with the polynucleotide of Group II and the antibody of Group III.

Lastly, the Examiner suggests that the method of Group V for identifying agents that increase or decrease activity of an RNase H polypeptide is drawn to screening a broad class of agents that include small molecule inhibitors, and involve steps such as measuring the activity of RNase H that are not shared with any other group.

The Examiner suggests that these inventions are distinct for the above reasons, and have acquired a separate status in the art, as shown by their different classification.

Applicants respectfully traverse this restriction requirement.

MPEP 803 states that for proper restriction (1) the claimed inventions are independent or distinct (2) search and examination

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of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

MPEP 808.01 states that where the inventions claimed are independent, i.e., where they are not connected in design, operation, or effect under the disclosure of the particular application under consideration, the facts relied on for this conclusion are in essence the reasons for insisting upon restriction. MPEP 802.1 defines "distinct" as two or more subjects as disclosed are related.

In the present invention, the claims relate to polypeptides which have been identified as novel human Type 2 RNase by homology between amino acid sequences (please see Specification page 6, lines 5-7) and antisense inhibition of expression of a target protein via the use of human Type 2 RNase H (please see Specification page 6, lines 26-28). By definition, the groups cannot be independent because the polypeptides share homology and Type 2 characteristics. Therefore, there is a disclosed relationship between the polypeptides.

Applicants respectfully request reconsideration and withdrawal of the restriction requirement.

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However, in an earnest effort to be fully responsive and facilitate prosecution of this application, Applicants elect to prosecute Group II, an isolated polypeptide encoding RNase H and compositions comprising pharmaceutical carriers or antisense with said RNase H polypeptide, and vectors, cells, and methods of use.

Applicants do not believe that claims 24-26 properly belong in Group II, as they are directed to methods of enhancing inhibition of a selected protein using an antisense oligonucleotide and a human Type 2 RNase H polypeptide, not a polynucleotide.

Respectfully submitted,

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Date: November 10, 2003

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